RESEARCH PLAN PROPOSAL

EFFECT OF MEDICAL NUTRITION THERAPY AND LIFESTYLE EDUCATION ON NUTRITIONAL AND HEALTH OUTCOMES OF CKD PATIENTS WITH AND WITHOUT DIALYSIS

For registration to the degree of
Doctor of Philosophy

IN THE FACULTY OF SCIENCE
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1. INTRODUCTION

1.1 KIDNEYS – GENERAL INFORMATION

1.1. i Anatomy and location

The kidneys are two bean-shaped organs, each about the size of a fist. They are located just below the rib cage, one on each side of the spine. Every day, the two kidneys filter about 120 to 150 quarts of blood to produce about 1 to 2 quarts of urine, composed of wastes and extra fluid. The urine flows from the kidneys to the bladder through two thin tubes of muscle called urethras, one on each side of the bladder. The bladder stores urine. The muscles of the bladder wall remain relaxed while the bladder fills with urine. As the bladder fills to capacity, signals sent to the brain tell a person to find a toilet soon. When the bladder empties, urine flows out of the body through a tube called the urethra, located at the bottom of the bladder. In men the urethra is long, while in women it is short (Ford, 2014).

1.1. ii Functions of kidney

The kidney is not one large filter. Each kidney is made up of about a million filtering units called nephrons. Each nephron filters a small amount of blood. The nephron includes a filter, called the glomerulus, and a tubule. The nephrons work through a two-step process. The glomerulus lets fluid and waste products pass through it; however, it prevents blood cells and large molecules, mostly proteins, from passing. The filtered fluid then passes through the tubule, which sends needed minerals back to the bloodstream and removes wastes.

Healthy kidneys handle several specific roles -

- Maintain a balance of water and concentration of minerals, such as sodium, potassium, and phosphorus, in blood.
- Remove waste by-products from the blood after digestion, muscle activity, and exposure to chemicals or medications.
- Produce renin, an enzyme that helps regulate blood pressure.
- Produce erythropoietin, which stimulates red blood cell production.
- Produce an active form of vitamin D, needed for bone health (Ford, 2014).

1.1. iii Renal (kidney) diseases and its types

When the kidneys become damaged, waste products and fluid can build up in the body, causing swelling in your ankles, vomiting, weakness, poor sleep, and shortness of breath. If left untreated, diseased kidneys may eventually stop functioning completely. Loss of kidney function is a serious and potentially fatal condition.

1.1.iii.a *Acute renal disease and its causes*

The sudden loss of kidney function is called acute kidney injury, also known as acute renal failure (ARF). ARF can occur following:

- A traumatic injury with blood loss
- The sudden reduction of blood flow to the kidneys
- Damage to the kidneys from shock during a severe infection called sepsis
- Obstruction of urine flow, such as with an enlarged prostate
- Damage from certain drugs or toxins
- Pregnancy complications, such as eclampsia and pre-eclampsia.

Marathon runners and other athletes who don't drink enough fluids while competing in long-distance endurance events may suffer acute renal failure due to a sudden breakdown of muscle tissue. This muscle breakdown releases a chemical called myoglobin that can damage the kidneys (Ford, 2014).

1.1.iii.b *Chronic renal disease and its causes*

Kidney damage and decreased function that lasts longer than 3 months is called chronic kidney disease (CKD). Chronic kidney disease is particularly dangerous because you may not have any symptoms until considerable, often irreparable, kidney damage has occurred. Diabetes (types 1 and 2) and high blood pressure are the most common causes of CKD. Other causes are:

- Immune system conditions such as lupus and chronic viral illnesses such as HIV/AIDS, hepatitis B, and hepatitis C.
- Urinary tract infections within the kidneys themselves, called pyelonephritis, can lead to scarring as the infection heals. Multiple episodes can lead to kidney damage.
- Inflammation in the tiny filters (glomeruli) within the kidneys; this can happen after strep infection and other conditions of unknown cause.
- Polycystic kidney disease , in which fluid-filled cysts form in the kidneys over time. This is the most common form of inherited kidney disease.
- Congenital defects, present at birth, are often the result of a urinary tract obstruction or malformation that affects the kidneys. One of the most common involves a valve-like mechanism between the bladder and urethra. These defects, sometimes found while a baby is still in the womb, can often be surgically repaired by an urologist.

- Drugs and toxins, including long-term exposure to some medications and chemicals, such as NSAIDs (non steroidal anti-inflammatory drugs), like ibuprofen and naproxen, and use of intravenous “street” drugs (Melinda, March 2014).

1.1.iv Stages of chronic kidney disease leading to renal failure

Table 1- Stages of chronic kidney disease

CKD Stage	**GFR level (mL/min/1.73 m^2)**
Stage 1	≥ 90
Stage 2	60 – 89
Stage 3	30 – 59
Stage 4	15 – 29
Stage 5	< 15

(National Kidney Foundation, USA, Oct 2014)

1.2. COMPLICATIONS

Kidney disease can affect almost every part of your body. Potential complications may include:

- Fluid retention, which could lead to swelling in your arms and legs, high blood pressure, or fluid in your lungs (pulmonary edema)
- A sudden rise in potassium levels in your blood (hyperkalemia), which could impair your heart's ability to function and may be life-threatening

- Heart and blood vessel disease (cardiovascular disease)
- Weak bones and an increased risk of bone fractures
- Anemia
- Decreased sex drive or impotence
- Damage to your central nervous system, which can cause difficulty concentrating, personality changes or seizures
- Decreased immune response, which makes you more vulnerable to infection
- Pericarditis, an inflammation of the sac-like membrane that envelops your heart (pericardium)
- Pregnancy complications that carry risks for the mother and the developing fetus
- Irreversible damage to your kidneys (end-stage kidney disease), eventually requiring either dialysis or a kidney transplant for survival (http://www.mayoclinic.org).

1.3 DIALYSIS

Dialysis is a process of removing waste products and excess fluid from the body and is used primarily as an artificial replacement for lost kidney function in people with renal failure. Dialysis allows patients with kidney failure a chance to live productive lives. There are two types of dialysis: hemodialysis and peritoneal dialysis. Each type of dialysis has advantages and disadvantages. Patients can usually choose the type of long term dialysis that best matches their needs. A properly functioning kidney helps prevent salt, extra water, and waste from accumulating in your body. It also helps control blood pressure and regulates important chemicals in the blood, such as sodium (salt) and potassium. When

kidneys don't perform these functions due to disease or injury, dialysis can help purify the blood and remove waste.

There are two different types of dialysis:

- **Hemodialysis** involves using an artificial kidney, known as a hemodialyzer, to remove waste and chemicals from the blood. It accesses the blood through a minor surgical procedure in the arm or leg, or through a plastic tube in the neck called a catheter.
- **Peritoneal dialysis** involves the surgical implantation of a catheter into your stomach area. During treatment, a special fluid called dialystate is pumped into the abdomen where it draws waste out of the bloodstream (Krans, 2012).

1.4 NUTRITIONAL REQUIREMENTS FOR DIALYSIS PATIENTS

Dialysis changes dietary needs. Patients undergoing typical hemodialysis, involving about three treatments per week, follow diets that are restricted in protein, sodium, potassium, phosphorus, and fluid. Patients on continuous ambulatory peritoneal dialysis, involving several dialysate exchanges per day, can be more liberal in protein, sodium, potassium and fluid intake.

1.4.i Sodium

Sodium intake must be modified to prevent hypertension, congestive heart failure, and pulmonary edema. Limiting intake will help avoid thirst and maintain acceptable fluid balance. Restrictions range from 1,000-3,000 milligrams per day with hemodialysis and 2,000-4,000 milligrams per day for peritoneal dialysis. Major salt sources are described below.

1.4.ii Fluid

Fluid consumption should be controlled to avoid congestive heart failure, pulmonary edema, hypertension, and swelling of the legs and feet. Fluid allowances are 1,000-1,500 milliliters per day and are based on urine output and type of dialysis.

1.4.iii Protein

Protein requirements range from 1.1-1.5 grams per kilogram, depending on the type of dialysis used and the patient's nutritional status. It is important to ensure sufficient protein to maintain visceral protein stores, but to avoid excesses that could lead the accumulation of nitrogenous waste products in the blood (uremia).

1.4.iv Phosphorus

Kidney failure causes high levels of phosphorus to build up in the blood and disrupts calcium/phosphorus balance. Elevated phosphorus levels can lead to metastatic calcification (soft tissue calcification), secondary hyperparathyroidism, and renal osteodystrophy. Recommended intakes usually range from 800-1,000 milligrams per day with hemodialysis and less than 1,200 milligrams per day with periotoneal dialysis.

1.4.v Potassium

Potassium restrictions depend on serum potassium levels, the type of dialysis, medications, and residual renal function. Patients on hemodialysis are usually restricted to 2,000-3,000 milligrams per day to prevent hyperkalemia between treatments. Patients on peritoneal dialysis may follow a more liberal dietary

potassium intake, as potassium is lost in the dialysate solution during daily exchanges (http//www. pcrm@pcrm.org).

1.5. PREVALENCE OF RENAL DISEASE

1.5.i World-wide

Whaley et al. (2009) had reported prevalence of chronic kidney disease (CKD) in U.S conducted by two agencies, i.e. Kidney Early Evaluation Program (KEEP) and National Health and Nutrition Examination Survey (NHANES). The survey was conducted between 1999 and 2006. The findings, according to KEEP, showed 26.2% individuals with CKD and according to NHANES 18.3% people were identified with CKD.

Isiki (2008) studied prevalence of chronic kidney disease in Japan. He revealed that about 2000 per million populations were found to be suffering from ESRD. The prevalence of low GFR (<60ml/min/1.73 m) was estimated to be 20% of the adult population. It was concluded that early detection and treatment of CKD are necessary to decrease the incidence of ESRD and CVD.

In another study, an international comparison of the relationship of chronic kidney disease, its prevalence and risk of ESRD was carried out by Hallon et al. (2006). They found that ESRD incidence is much lower in Europe compared with the United State (US). The relative risk for progression from CKD stages 3 or 4 to ESRD in US white patients was 2.5 when compared with Norwegians patients. This was only modestly modified by adjustment for age, gender and diabetes.

Coresh et al. (2005) conducted a study to assess the awareness of CKD in US population from 1999 to 2000 and determined whether the prevalence of CKD in

US increased as compared to that from 1988 to 1994. They concluded that despite a high prevalence of CKD, its awareness in the US population is low. In contrast to the dramatic increase in treated kidney failure, over all prevalence of CKD in the US population has been relatively stable.

In another study prevalence of chronic kidney disease was assessed by Obrador et al.(2002) and the findings revealed that around 6.2 million individuals to have serum creatinine level at or above 1.5mg/dl and 8.3 million individual having decreased glomerular filtration rate (<60ml/min/1.73m^2). The average number of persistently elevated serum creatinine level was found in 4.2 million Americans.

1.5.ii India

The SEEK (Screening and Early Evaluation of Kidney Disease) study was conducted by Singh et al. (2013) to know the prevalence of kidney disease in India. According to the findings incidence rate of ESRD was found to be 229 per million population and more than 1,00,000 new patients entered renal transplant programmes annually. Over all prevalence was 17.2% of CKD and as per stages 1, 2, 3, 4 and 5 incidence was 7% , 4.3% , 4.3% , 0.8% and o.8%, respectively.

A study on current status of ESRD care in India and Pakistan was carried out by Jha in 2013. A population based study calculated 152 incidences per million populations and diabetic kidney disease was found to be the commonest one in India.

Agarwal et al. (2005) conducted a multi cluster sampling in South Delhi. Collected data revealed CRF to be present in 37 individuals out of 4712. Thus, the prevalence of CRF in the selected adult population was around 0.78% or 7852/million.

1.6 RISK FACTORS AND ETIOLOGY

Leoncini et al. (2010) revealed correlation between chronic kidney disease (CKD) and hypertension in Italian subjects. The presence of CKD was associated with higher systolic and pulse pressure levels. It was also found to be associated with older age, smoking, impaired fasting glucose, hyperuricemia and previous cardiovascular disease.

Robert (2005) worked on the epidemiology of chronic kidney disease. They concluded that diabetes and hypertension both are the major causes for ESRD. They also stated that the prevalence of diabetes induced ESRD will become almost double in the next 25 years.

Toto (2005) revealed hypertension to be present in more than 80% of the patients having CKD and contributes to progression of kidney disease towards end stage renal disease (ESRD).

Factors that may increase your risk of chronic kidney disease include:

- Diabetes
- High blood pressure
- Heart disease
- Smoking
- Obesity
- High cholesterol
- Being African-American, Native American or Asian-American
- Family history of kidney disease
- Age 65 or older (http://www.mayoclinic.org).

1.7. NUTRITIONAL STATUS AND PROBLEM OF MALNUTRITION AMONG DIALYSIS PATIENTS

Loalris (2014) conducted a study to assess renal function in patients on long-term home parenteral nutrition and in intestinal transplant recipients. He found that the frequency of CRF was 6% in the home parenteral nutrition (HPN) group and 9% in the intestinal transplantation (ITx) group, as well as the decrease of renal function and the risk for developing CRF were greater after ITx than during HPN.

In a comparative study on the nutritional status of peritoneal dialysis (PD) and hemodialysis patients (HD) in Korea, Park, *et al*. (1999) found that higher incidence of malnutrition in PD patients than in HD patients (33% v 18%) and in diabetics than in non diabetics. It was also revealed that in malnourished PD and HD patients, percentage IBW, serum albumin, dietary energy and protein intake were significantly lower than in well-nourished counterparts.

Kopple, 1997 studied the nutritional status to be a predictor of morbidity and mortality in maintenance dialysis patients and the findings revealed primary predictor of malnutrition to be energy protein imbalance. Low predialysis serum creatinine, cholesterol, potassium, phosphorus, calcium, and bicarbonate also correlated with the same.

2. SIGNIFICANCE AND BROAD OBJECTIVES

2.1 SIGNIFICANCE

Renal failure and end stage renal disease are enormous medical problems that require the expenditure of huge resources. Undernutrition is a major negative prognostic factor in dialysis patients. In addition, undernutrition is associated with increased morbidity and mortality in these patients. A number of interventions have been undertaken worldwide to increase nutrient intake or to provide growth factors to induce anabolism, but in Indian context, very few researches have been undertaken.

A recent research was conducted by Anjali and Veenu Seth (2014) in Delhi, on the nutritional status of diabetic nephropathy patients undergoing hemodialysis. They found that the nutritional status of those patients was very poor because of poor dietary intake and nutritional inadequacy. It was also stated that every maintenance dialysis patient needs an intensive nutritional counseling based on an individualized plan of care developed before or at the time of commencement of maintenance dialysis therapy.

Many interventions have been done and have met with varying degrees of success. The most efficient and effective method of managing undernutrition in the dialysis patient is still unclear. More research is needed to determine the most appropriate method of management of undernutrition. Although developments in medical technology, pharmacology, and nutritional science continue to improve treatment possibilities for patients with renal failure, the level of compliance with medical and dietetic advice remains poor. Previous researches on compliance with treatment of chronic illness has led to recommendations for an improved

understanding of what is involved in living with chronic illness in order to tailor treatment more appropriately to individual needs.

This qualitative study sets out to examine, the experiences and difficulties of patients on dialysis who follow dietary restrictions, and to ascertain how the dietitian can most effectively support patients in adapting to dietary change because a dialysis diet plan plays a very important role to the health of a person undergoing maintenance dialysis. This is because a patient with dialysis must eat the right kind of food. An individual dialysis diet plan as well as non dialysis, is important because not following one can make their condition worse. Kidney malfunction is a life threatening condition, so utmost care and discipline is crucial, especially when it comes to food intake. Additionally, the type of dialysis diet plan one should follow, depends on the severity of the disease, age, sex, type of dialysis as well as the treatment undertaken. So when planning the dialysis diet chart, dietitian must take into account these considerations of status or stage of kidney disease.

Dietary counseling, as well as lifestyle management practices also plays important role in dialysis patients because most of the renal patients suffers also from one of the non communicable diseases like diabetes mellitus, hypertension, pulmonary disease and cancer. So lifestyle management counseling will be fruitful for these patients.

In present study, regular assessment of nutritional status of patients who are not on dialysis as well as undergoing maintenance dialysis will be done after four weeks and then after eight weeks. Every maintenance dialysis patient and non dialysis renal patient will be given an intensive nutritional counseling based on an individualized plan of care developed before or at the time of commencement maintenance dialysis therapy. Simple and reliable biochemical estimations of nutritional status will be carried out, so it would be beneficial to identify patients at

severe undernutrition risk, and for knowing impact of counseling. So this study would be beneficial for the renal community, which is undergoing maintenance dialysis and not on dialysis and not having sufficient knowledge regarding diet and lifestyle management. This research will also be useful to improve their nutritional status by continuous counseling, monitoring and follow up plans.

Further, in the present study, an effort will be made to create a database of electrolytes (sodium, potassium) and phosphorus content, present in various raw, processed and packaged food products. This will be done because there are various raw and packaged foods available in the market, of which nutrient values for phosphorus, sodium and potassium are not given by ICMR, 1989. Besides this, values of these nutrients are not also mentioned on the label of various processed and packed food products.

Therefore, while taking the food intake data of renal patients, it becomes difficult for researcher to calculate the actual intake of these micronutrients. Thus in the present study, it becomes essential to create a database of the foods of which values for phosphorus sodium and potassium are not available as all these micronutrients play an important role in kidney functions.

2.2 BROAD OBJECTIVES

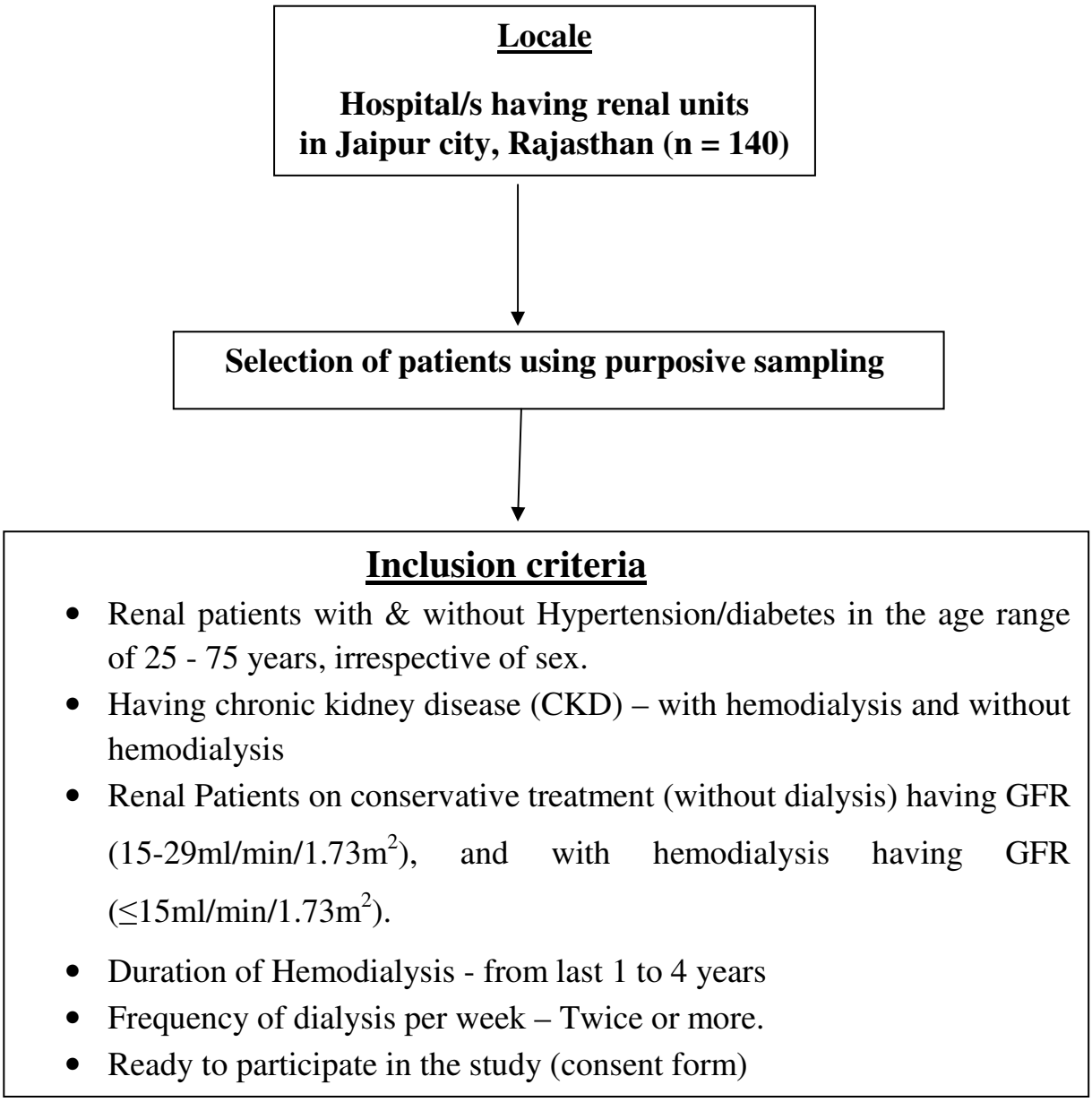
Phase 1

1. To create database of electrolytes (sodium, potassium) and phosphorus content of various raw, processed and packaged food products used for renal patients.

Phase II

1. To assess the nutritional status of chronic kidney disease patients with or without hemodialysis from hospital/s having renal units in Jaipur city, Rajasthan.
2. To conduct nutrition and lifestyle education intervention program for a period of 3 months at 2 stages and study its impact on the health and nutritional status of renal patients, with and without hemodialysis.

3. METHODOLOGY


Locale
Hospital/s having renal units in Jaipur city, Rajasthan (n = 140)
Selection of patients using purposive sampling
Inclusion criteria
• Renal patients with & without Hypertension/diabetes in the age range of 25 - 75 years, irrespective of sex.
• Having chronic kidney disease (CKD) – with hemodialysis and without hemodialysis
• Renal Patients on conservative treatment (without dialysis) having GFR (15-29ml/min/1.73m2), and with hemodialysis having GFR (≤15ml/min/1.73m2).
• Duration of Hemodialysis - from last 1 to 4 years
• Frequency of dialysis per week – Twice or more.
• Ready to participate in the study (consent form)

PHASE I

Create database on phosphorus, and electrolyte (sodium, potassium) content of foods

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Selection of various raw and processed food stuffs commonly consumed by population from local market

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Estimation of phosphorus, by UV Spectrophotometer and electrolytes (sodium, potassium) by flame photometer

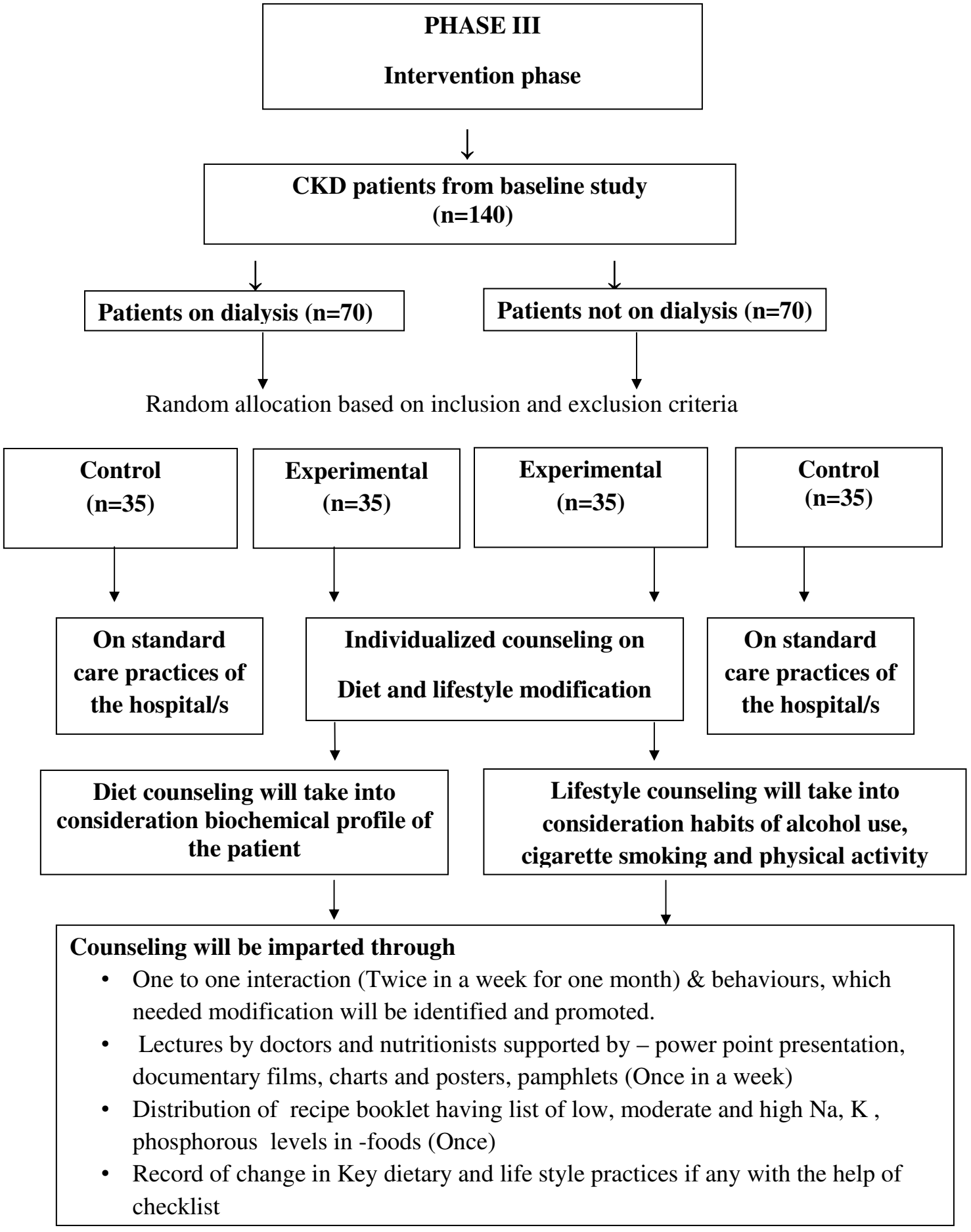
PHASE II

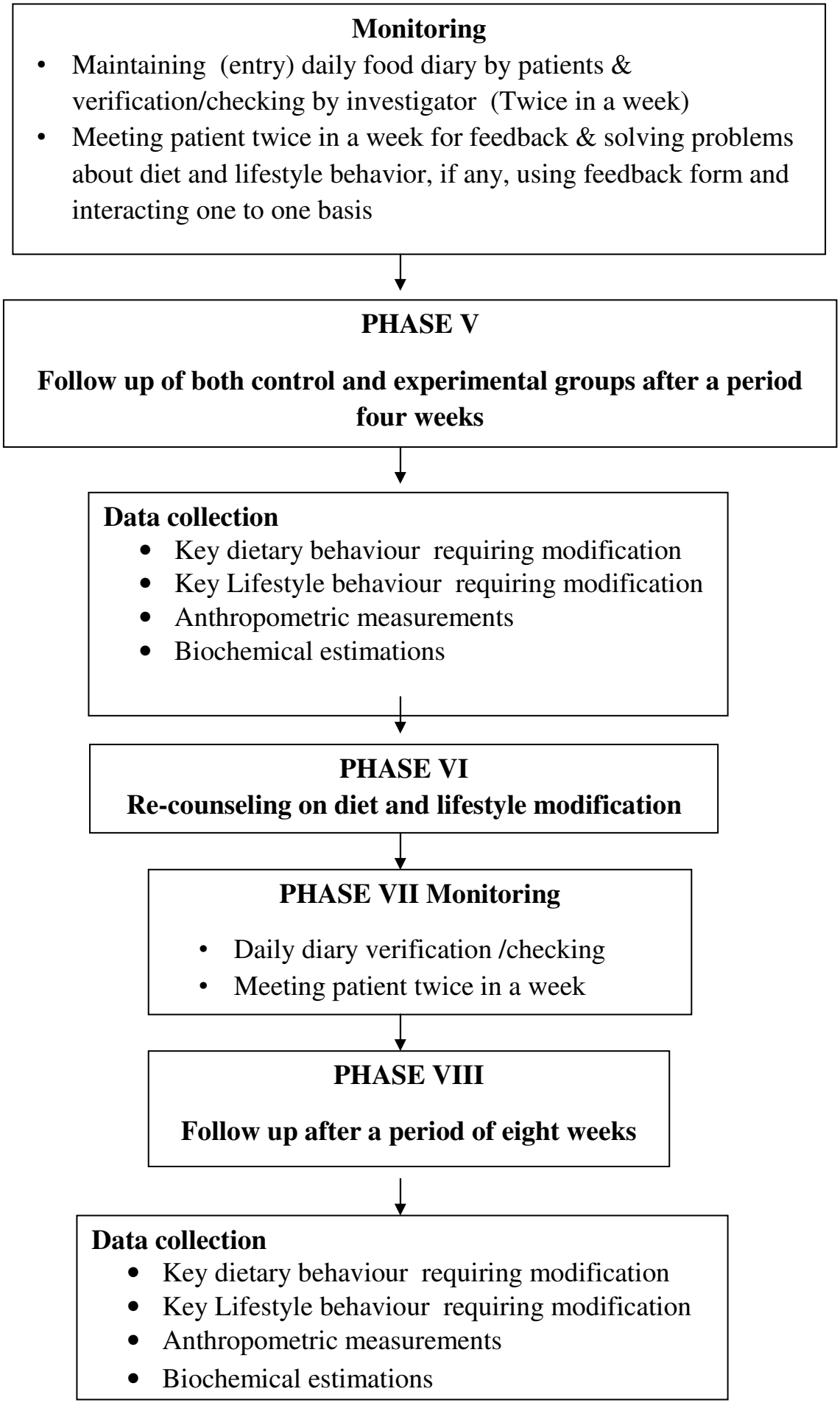
Baseline study (n = 140 including drop outs.) Samples will be selected by purposive sampling and patients who will fulfill inclusion criteria will be seleced.

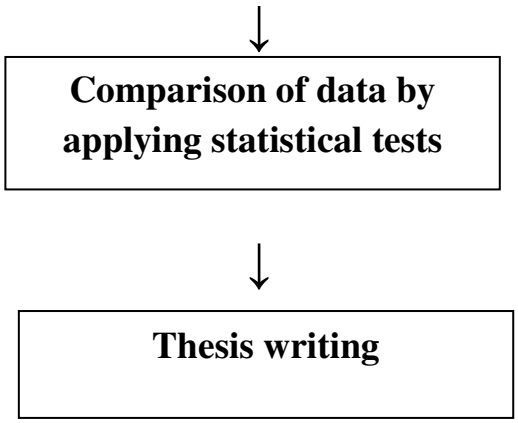
↓

Data collection (Using interview schedule)

- General information (name, age, sex, address, socioeconomic status, type of job, type of family, caste, religion, etc.)
- Dietary pattern (meal pattern and food consumption, frequency with reference to electrolytes, phosphorous and protiens) and lifestyle (alcohol consumption habits, cigarette smoking habits, activity pattern)
- Anthropometric measurement (BMI, waist hip ratio/waist circumference)
- Biochemical estimations (case reports of total blood cholesterol and triglyceride, serum albumin and globulin, serum creatinine, electrolytes, calcium, phosphorus and iron, hemoglobin, blood urea nitrogen, fasting blood sugar & PP)
- Medical history (duration of the disease, etiology, associated diseases, list of medications, type of dialysis and frequency of the dialysis in a week.)


PHASE III
Intervention phase
CKD patients from baseline study (n=140)
Patients on dialysis (n=70)
Patients not on dialysis (n=70)
Random allocation based on inclusion and exclusion criteria
Control (n=35)
Experimental (n=35)
Experimental (n=35)
Control (n=35)
On standard care practices of the hospital/s
Individualized counseling on Diet and lifestyle modification
On standard care practices of the hospital/s
Diet counseling will take into consideration biochemical profile of the patient
Lifestyle counseling will take into consideration habits of alcohol use, cigarette smoking and physical activity
Counseling will be imparted through
• One to one interaction (Twice in a week for one month) & behaviours, which needed modification will be identified and promoted.
• Lectures by doctors and nutritionists supported by – power point presentation, documentary films, charts and posters, pamphlets (Once in a week)
• Distribution of recipe booklet having list of low, moderate and high Na, K , phosphorous levels in -foods (Once)
• Record of change in Key dietary and life style practices if any with the help of checklist


Monitoring
• Maintaining (entry) daily food diary by patients & verification/checking by investigator (Twice in a week)
• Meeting patient twice in a week for feedback & solving problems about diet and lifestyle behavior, if any, using feedback form and interacting one to one basis
PHASE V
Follow up of both control and experimental groups after a period four weeks
Data collection
• Key dietary behaviour requiring modification
• Key Lifestyle behaviour requiring modification
• Anthropometric measurements
• Biochemical estimations
PHASE VI
Re-counseling on diet and lifestyle modification
PHASE VII Monitoring
• Daily diary verification /checking
• Meeting patient twice in a week
PHASE VIII
Follow up after a period of eight weeks
Data collection
• Key dietary behaviour requiring modification
• Key Lifestyle behaviour requiring modification
• Anthropometric measurements
• Biochemical estimations


Comparison of data by applying statistical tests
Thesis writing

For the present study, chronic kidney disease patients with and without dialysis, will be selected for the nutrition and lifestyle intervention.

3.1 LOCALE OF THE STUDY

The study will be conducted in Jaipur city, Rajasthan. The hospital/s having renal units will be enlisted then selection of the hospital/s will be done.

3.2 SAMPLE SELECTION

The sample of the study will constitute 140 chronic kidney disease (CKD) patients, will be based on purposive sampling. This number (140) will take care of those who may drop out due to some or the other reason during the period of study. Out of these 140 patients 70 patients will be with hemodialysis and 70 patients without dialysis. The selected patients should fulfill the inclusion criteria and should be willing to participate in the study. The data related to knowledge of the patients about the renal disease, dialysis, their anthropometric measurements, biochemical estimations, complications, dietary pattern and lifestyle will be collected using an interview schedule.

3.2.i Inclusion criteria

- Renal patients with & without Hypertension/diabetes in the age range of 25 - 75 years, irrespective of sex.
- Having chronic kidney disease (CKD) – with hemodialysis and without hemodialysis
- Renal Patients on conservative treatment (without dialysis) having GFR (15 -29ml/min/1.73m^2), and with hemodialysis having GFR ($\leq$15ml/min/1.73m^2).
- Duration of Hemodialysis - from last 1 to 4 years
- Frequency of dialysis per week – Twice or more.

- Ready to participate in the study (consent form)

3.2.ii Exclusion criteria

- Patients with age below 25 years and above 75 years
- Continuous ambulatory peritoneal dialysis (CAPD) patients
- Unconscious patients and cancer patients
- Patients on Total parentral nutrition (TPN) or Peripheral parenteral nutrition (PPN)
- Not on medication
- Having dialysis less than two times in a week

3.3 STUDY DESIGN

The present study will be carried out in the following phases:

3.3.i) PHASE I

In phase 1, database on electrolytes (sodium, potassium) and phosphorus content of various raw and processed foods will be developed by taking nutrient values given by ICMR, 1989 for these nutrients and in case, if the values of these nutrients are not available, then estimation will be carried out in the laboratory of the University, using standard techniques and chemicals of analytical grades. Food samples will be collected from the local market of Jaipur city. Samples will be selected based on the foods commonly recommended for renal disease patients or commonly consumed by population including nutrition supplements prescribed for renal patients.

For estimation of phosphorus, by UV Spectrophotometer method (AOAC, 2005) and for potassium and sodium, by Flame photometer method (AOAC, 2005) will be followed.

3.3.ii) PHASE II: **The baseline study (Pre intervention knowledge testing phase)**

The baseline study will be carried out on 140 renal patients, with and without hemodialysis. An interview schedule will be used to collect information related to disease knowledge, dietary pattern, anthropometric measurements, biochemical estimations, lifestyle, and medical history of the renal patients. Standard tools and techniques will be used to collect data.

Disease knowledge: In this section, questions regarding disease knowledge of the patients will be asked. On the basis of this knowledge, educational material for imparting counseling will be developed.

Anthropometric measurements: Anthropometric measurements will include measurement of height, weight, hip circumference and waist circumference data. The collected data will be used to calculate BMI, waist hip ratio / WC of the patients.

Life style data: This will include habits related to alcohol consumption, cigarette smoking, activity pattern, and type of physical activity of the patients. CDC, Atlanta tool will be used for measuring physical activity of the patients.

Medical history: The complete medical history will be taken from the patient regarding duration of the disease, etiology, associated diseases, medication, type of dialysis and frequency of the dialysis in a week.

Biochemical estimations: The laboratory data on total serum cholesterol and triglyceride, serum creatinine, serum albumin and globulin, serum electrolytes, calcium, phosphorus and iron, blood hemoglobin level, blood urea nitrogen and

random blood sugar level of the patients will be collected from their medical reports. The medical reports of the patients will be referred for data on-

- Total cholesterol(mg/dl)- <200
- Serum triglycerides(mg/dl)- <160
- Serum creatinine (mg/dl) - 0.5-1.2
- Serum albumin (g/dl) - 3.5-5.0
- Serum globulin (g/dl) - 2.0-3.5
- Sodium (mEq/l) - 135-145
- Potassium (mEq/l) - 3.5-5.0
- Serum calcium (mg/dl) - 9.0-11.0
- Serum iron (µg/dl)- 50-150
- Serum phosphorus(mg/dl) - 3.5-5.5
- Blood urea nitrogen (mg/dl)- 10-20
- Hemoglobin (g/dl) - 13-15 (for female), 15-17 (for male)
- Fasting blood sugar (mg/dl) - 75-100
- Blood sugar PP (mg/dl) - >150 (Algappan, 2014)

Dietary assessment: Dietary pattern data will include food habits (vegetarian/non-vegetarian/eggetarian) and frequency of food consumption (weekly/monthly/annually). An interview schedule will be prepared for recording food consumption frequency of the patient, the patient will be asked about frequency of foods consumed by them, their proportion and recipes usually followed. This method will be very useful to predict individual's intake and to assess the relationship between diet and disease. The patient will be asked about different food items consumed by him to assess intake per day or per week or per month.

Pilot study- A pilot study will be conducted on 5 patients for pretesting of interview schedule. After pretesting, the required modifications will be made in the interview schedule and then it will be used for collecting data on the selected sample.

3.3.iii) PHASE III- Intervention phase

3.3.iii.a) ***Sample for intervention phase***

The total sample of 140 patients (70 undergoing hemodialysis and 70 non-dialysis patients) will be further divided into control and experimental groups (35 in each group). The intervention study will be conducted on 70 patients (35 dialysis patients and 35 non dialysis CKD patients), selected for baseline study from the hospital/s.

The patients in the control and experimental groups will be allocated according to their GFR rate and the frequency of dialysis per week. GFR rate will be calculated at the time of baseline data collection. The patients will be randomly divided into control and experimental groups after matching for GFR rate and periodicity of dialysis per week.

The patients falling in the Experimental groups (dialysis and non dialysis) will be provided extensive dietary counseling (twice in a week) on one to one basis by the investigator and the counseling will be based on their existing biochemical profile. Lifestyle counseling will take into consideration habits of alcohol use, cigarette smoking and physical activity.

3.3.iii.b) Diet and lifestyle intervention programme

The diet and life style intervention (counseling) will focus on-

- Information related to renal disease, dialysis and associated diseases and complications
- Dietary modification
- Lifestyle modification
- Importance of maintaining optimal weight

The nutrition and lifestyle intervention programme will include one to one interaction of the investigator with the patient, sessions comprising lectures by doctors and nutritionists on lifestyle and dietary modification, documentary films will be screened in a group on the awareness of the disease progression and healthy lifestyle habits, awareness of the risk factors by using charts and posters, pamphlets and bookmarks on healthy eating, and power point presentations. Recipe booklet will be given to all the patients for adding variety in their daily meals.

After counseling, an individualized diet chart will be given to the patients by the investigator, prepared as per the patient's requirement. A food diary will also be provided to the patients for noting down the daily meal pattern over a period of 28 days/ 4 weeks.

3.3.iv) PHASE IV- Monitoring

- The patients who will undergo nutrition intervention programme will be monitored by personal meetings twice in a week, phone calls and verification of daily food diary for a period of four weeks. After meeting patients, feedback will be taken to assess their knowledge using feedback form and interacting on one to one basis.

3.3.v) PHASE V- First follow up of both control and experimental groups after a period of one month (post intervention knowledge testing phase)

After a period of four week intervention and monitoring, data of the subjects will again be collected with regard to anthropometric measurements, biochemical estimation, and dietary pattern. The collected data will then be compared with baseline data.

3.3.vi) PHASE VI- Re-counseling on diet and lifestyle modification

Re-counseling will be done according to new biochemical estimation reports.

3.3.vii) PHASE VII- Monitoring

Subjects following nutrition intervention programme will be again monitored by weekly personal meetings, phone calls and filling of daily diary for a period of eight week.

3.3.viii.) PHASE VIII- Second follow up

After eight weeks of first follow up, second follow up data will be collected. The data of the subjects would again be collected with regards to anthropometric measurements, biochemical estimations and dietary intake, and life style habits. The data will then be compared with baseline data and first follow up data.

3.4 STATISTICAL ANALYSIS

The entire data will be finally be tabulated and statistically analyzed using appropriate statistical tests, *viz*. mean and standard deviation, Z test, chi-square test, correlation, etc.

3.5 THESIS WRITING

References

- Agarwal, S. K., Dash, S. C., Irshad, M., Raju, S., Singh, R., Pandey, R. M., (2005). Prevalence of chronic renal failure in adults in Delhi, India. *Nephrology Dialysis Transplant.* 20 (8): 1638-1642.
- Algappan, R., Manual of Practical Medicine (5th edition), 779-780.
- Anjali, Seth.V., (2015). The Nutritional Status of Diabetic Nephropathy Patients Undergoing Hemodialysis at New Delhi Hospital, India: A Pilot Study. *International Journal of Food Science Nutrition and Dietetics*. 04(1), 178-182.
- Coresh, J., Byrd-Holt, d., Astor, B. C., Briggs, J. P., Eggers, P. W., Lacher, D. A., Hoetetter, T. H., (2005). Chronic kidney disease awareness, prevalence, and trends among U.S. adults, 1999 to 2000. *Journal of American Society of Nephrology*. 16(1):180-8.
- Hallon, S. I., Coresh, j., Astor, B. C., Asberg, A., Powe, N. R., Romundstad, S., Holmen, J., (2006). International comparison of the relationship of chronic kidney disease prevalence and ESRD risk. *Journal of American Society Nephrology.* 17(8):2275-84.
- Indridason, O.S., Thorsteinsdottir, I., Palsson, R., *Laeknabladid*. 93(3):201-7.
- Iseki, K., (2008). Chronic kidney disease in Japan. *Internal Medicine.* 47(8):681-9.
- Jha, V., (2013). Current status of end-stage renal disease care in India and Pakistan. *Kidney International Supplements*. 3, 157–160; doi:10.1038.
- Jha. V., (2004). End-stage renal care in developing countries: the India experience. *Renal Failure.* 26(3):201-8.

- Khanna, U., (2009). The Economics of Dialysis in India. *Indian jouranal of nephrology.* 19(1): 1–4.
- Kopple, J. D., (1996). Nutritional status as a predictor of morbidity and mortality in maintenance dialysis patients. *American society of internal organ journal.* 43(3):246-50.
- Leoncini, G., Viazzi, E. A., Ambrosioni, E., Costa, F. V., Leonetti, G., Pessina, A. C., Trimarco, B., Volpe, M., Deferrari, G., pontremoli, R., (2010). Chronic kidney disease in hypertension under specialist care: the I-DEMAND study. *Journal of hypertension.* 28(1):156-62.
- Obrador, G. T., Pereia, B. J., Kausz, A. T., (2002). Chronic kidney disease in the United States: an under recognized problem. *Seminar in Nephrology*. 22(6):441-8.
- Park, Y. K., Kim, J. H., Kim, K. J., Seo, A. R., Kang, E. H., Kim, S. B., Park, S. K., Park, J. S., A cross-sectional study comparing the nutritional status of peritoneal dialysis and hemodialysis patients in Korea. *Journal of renal nutrition*. 9(3):149-56.
- Satyavani, K., Othandan, H.K., Jayaraman, M., Viswanathan, M., (2014). Burden of CKD in India. *Indian jouranal of nephrology* 24 (3) :141-147.
- Singh. A. K., Youssef, M. K., Bharati, F. V. M., Kuyilan, K. S., Sai, R. K., Reddy, V. N., Acharya, A. F.A., Channakeshavamurthy, A., Ballal, H. S., Gaccione, P., Rajan, I., Jasuja, S., Kirpalani, A. L., Kher, V., Modi, G. K., Nainan, G., Prakash, J., Rana, D.S., Sreedhara, R., Sinha, D. K., Shah, B. V., Shamsunder, Raj, K.S., Sridevi, S., Tatapudi, R. R., and Rajapurkar, M.M., (2013). Epidemiology and risk factors of chronic kidney disease in India – results from the SEEK (Screening and Early Evaluation of Kidney

Disease) study. *Bio Medical Central Nephrology*. 14:114 doi:10.1186/1471-2369-14-114

- Toto, RD., (2005). Treatment of hypertension in chronic kidney disease. *Seminars in Nephrology*. 25(6):435-9.
- Whaley-onnell, A., Sowers, J. R., McCullough, P. A., Roberts, T., McFarlane, S. I., Chen, S. C., Li, S., Wang, C., Collins, A. J., Bakris, G. L., KEEP Investigators, (2009). *American Journal of Kidney Disease.* 53(4 Suppl 4):S11-21.

- "Complications" (Feb 2015). http://www.Mayoclinic.org/diseases-http://www.mayoclinic.org/diseases-conditions/kidney-disease/basics/complications/con-20026778 .
- "Nutrition and Renal Disease" (18 Nov 2014). http//www.. pcrm@pcrm.org
- "Risk factors" (Feb 2015). http://www.mayoclinic.org/diseases-conditions/kidney-disease/basics/risk-factors/con-20026778.
- Brian Krans, "Dialysis" (July 16, 2012) http://www.healthline.com /health/dialysis#Overview1
- Ford, (2014).http://www.academia.edu
- http://www.medicinenet.com/script/main/art.asp?articlekey=2980
- Melinda, R. (2014). http://www.webmd.com